

Serial No. 09/646,852, filed Sept. 22, 2000
Docket No. 1103326-0636
Page 2 of 10

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (Currently amended) A delayed release oral pharmaceutical dosage form comprising a core material coated with a semipermeable membrane, wherein:

the core material comprises an active ingredient selected from the group consisting of omeprazole, an alkaline salt of omeprazole, *S*-omeprazole and an alkaline salt of *S*-omeprazole, one or more alkalizing additives [agents], one or more swelling agents, an optional starter seed and optional pharmaceutically acceptable excipients;

the semipermeable membrane comprises [consists of] a single polymer composition containing a water-insoluble polymer capable of forming a semipermeable membrane and a modifying agent, wherein the semipermeable membrane [and] is able to disrupt; and

the dosage form is not enteric coated;

~~wherein the modifying agent and water insoluble polymer are present in a weight ratio of from 90:10 to 50:50, and wherein the alkalizing agent is an alkaline additive present in an amount of approximately 10 to 35% by weight of the core material excluding the weight of the optional starter seed.~~

Claim 2 (cancelled)

Claim 3 (Previously presented) The dosage form according to claim 1, wherein the active ingredient is omeprazole.

Claim 4 (Previously presented) The dosage form according to claim 1, wherein the active ingredient is a magnesium salt of omeprazole having a crystallinity of more than 70% as determined by X-ray powder diffraction.

Claim 5 (Previously presented) The dosage form according to claim 1, wherein the active ingredient is a magnesium salt of *S*-omeprazole.

Serial No. 09/646,852, filed Sept. 22, 2000

Docket No. 1103326-0636

Page 3 of 10

Claim 6 (Currently amended) The dosage form according to claim 1, wherein the core material comprises a starter seed layered with a suspension or solution of the active ingredient, one or more alkalizing additives [agents], one or more swelling agents and optionally pharmaceutically acceptable excipients.

Claim 7 (Previously presented) The dosage form according to claim 1, wherein the dosage form comprises individual pellets of the core material coated with the semipermeable membrane.

Claim 8 (Previously presented) The dosage form according to claim 1, wherein the core material further comprises an osmotic agent.

Claim 9 (Previously presented) The dosage form according to claim 1, wherein the alkaline additive gives a pH of not less than 8.5 when measured in a 2% w/w water solution/dispersion with a pH-measuring electrode.

Claim 10 (Previously presented) The dosage form according to claim 9, wherein the alkaline additive is selected from the group consisting of disodium hydrogen phosphate, trisodium phosphate, arginine and talc.

Claim 11 (canceled)

Claim 12 (Previously presented) The dosage form according to claim 1, wherein the alkaline additive is present in an amount of 15 to 35% by weight of the core material excluding the weight of the optional starter seed.

Claim 13 (Previously presented) The dosage form according to claim 1, wherein the swelling agent is selected from the group consisting of crosslinked polyvinyl pyrrolidone, crosslinked sodium carboxymethylcellulose, sodium starch glycolate and low-substituted hydroxypropyl cellulose (L-HPC).

Serial No. 09/646,852, filed Sept. 22, 2000
Docket No. 1103326-0636
Page 4 of 10

Claim 14 (Previously presented) The dosage form according to claim 1, wherein the swelling agent is present in an amount of approximately 20 to 60% by weight of the core material excluding the weight of the optional starter seed.

Claim 15 (Previously presented) The dosage form according to claim 1, wherein the swelling agent is present in an amount of 30 to 50% by weight of the core material excluding the weight of the optional starter seed.

Claim 16 (Previously presented) The dosage form according to claim 1, wherein the modifying agent is talc or fumed silica.

Claim 17 (Previously presented) The dosage form according to claim 1, wherein the water insoluble polymer is selected from the group consisting of ethylcellulose, cellulose acetate, polyvinyl acetate, and ammonio methacrylate copolymer type A and type B.

Claim 18 (Previously presented) The dosage form according to claim 1, wherein the water insoluble polymer is present in an amount of approximately 3-30% by weight of the core material.

Claim 19 (canceled)

Claim 20 (Previously presented) A process for the manufacture of a delayed release dosage form as defined in claim 1, comprising forming the core material, and coating the core material with a semipermeable membrane to obtain the delayed release dosage form of claim 1.

Claim 21 (canceled)

Claim 22 (canceled)

Serial No. 09/646,852, filed Sept. 22, 2000

Docket No. 1103326-0636

Page 5 of 10

- Claim 23 (Previously presented) A method for improving inhibition of gastric acid secretion which comprises administering to a patient in need thereof, a delayed release oral pharmaceutical dosage form according to any one of claims 1, 3-10, 12-18, 28 or 29.
- Claim 24 (Previously presented) A method for improving the therapeutic effect in the treatment of gastrointestinal disorders associated with excess acid secretion which comprises administering to a patient in need thereof, a delayed release oral pharmaceutical dosage form according to any one of claims 1, 3-10, 12-18, 28 or 29.
- Claim 25 (Previously presented) A delayed release oral dosage form according to any one of claims 1, 3-10, 12-18, 28 or 29 filled in a capsule.
- Claim 26 (Previously presented) A delayed release oral dosage form according to any one of claims 1, 3-10, 12-18, 28 or 29 compressed into a multiple unit tableted dosage form, optionally comprising tablet excipients.
- Claim 27 (Previously presented) The dosage form according to claim 12 or 13, wherein the core material further comprises an osmotic agent.
- Claim 28 (Previously presented) The dosage form according to claim 1, wherein the modifying agent and water insoluble polymer are present in a weight ratio of from 80:20 to 60:40.
- Claim 29 (Previously presented) The dosage form according to claim 1, wherein the starter seed is a sugar sphere.
- Claim 30 (New) The dosage form according to claim 1, wherein the alkaline additive is present in an amount of approximately 5 to 35% by weight of the core material excluding the weight of the optional starter seed.
- Claim 31 (New) The dosage form according to claim 1, wherein the modifying agent and water insoluble polymer are present in a weight ratio of from 90:10 to 50:50.